

### **REMARKS**

This Request for Reconsideration is being filed in response to the Office Action dated December 2, 2008. Claims 12-22 are currently pending in the application, all of which stand rejected. Of these, claims 12 and 16 are independent. Also included with this Request is the Declaration of Wallis Farraday Under 37 C.F.R. 1.132. Wallis Farraday is the named inventor of the present Application, and is at least one of ordinary skill in the art. As established in the annexed Declaration, and as described in more detail below, one of ordinary skill in the art reading the specification as originally filed would understand that the application is directed to a non-weight bearing post-operative dressing for a limb, and that the post-operative dressing is designed to be applied within 10 days of amputation of the limb. With this foundation, Applicant respectfully requests reconsideration in light of the Declaration of Wallis Farraday Under 37 C.F.R. 1.132 and the remarks set forth herein.

#### **Rejection under 35 U.S.C. §112, First Paragraph**

Claims 12 and 16 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action at pages 2-3 alleges that the specification does not provide sufficient support for the previous amendments to claims 12 and 16, which were amended to recite that the post-operative dressing of the present invention was a non-weight bearing device that was to be applied within 10 days of amputation.

In response, Applicant submits the annexed Declaration of Wallis Farraday Under 37 C.F.R. 1.132 ("The Farraday Declaration"). Wallis Farraday is the named inventor of the present Application and is an employee of the assignee, Hanger Orthopedic Group, Inc. Farraday Declaration ¶1. Mr. Farraday has a Prosthetics equivalent degree from the Central Institute of

Technology, New Zealand, as recognized by World Education Services, New York and has over 32 years of experience in orthopedic devices, specifically lower extremity prosthetics and management systems such as those disclosed, described and claimed in the subject Application. Farraday Declaration ¶2. Based on his education and experience, Mr. Farraday is at least one of ordinary skill in the art to which the Application pertains. Farraday Declaration ¶2.

As Mr. Farraday declares, it would be clear to one of ordinary skill in the art that the Application as filed is directed towards a non-weight bearing post-operative rigid protective dressing for a limb, and that the post-operative dressing is designed to be applied in the operating room or recovery rooms immediate post surgery or within 10 days of amputation of the limb. Farraday Declaration ¶¶ 3-7. Support for such an understanding is evidenced from at least the following.

One of ordinary skill in the art, upon reading the Application, would understand that the device disclosed in the Application is directed towards “an immediate post-operative limb protection dressing.” Farraday Declaration ¶ 5, citing paragraphs 2, 10, 25 and 27 of the Application, by way of example. In addition, the Application describes how the “rehabilitation team” applies the dressing after amputation, and that the dressing is designed to “enhance residual limb definition and accelerate rehabilitation time.” Farraday Declaration ¶ 5, citing paragraphs 9 and 11 of the Application, by way of example. The Application also describes how the dressing is designed to reduce and/or prevent flexion contractures, protect the limb from trauma, and negate external influences on healing, and to provide for easy quick inspection of the limb during initial postoperative care. Farraday Declaration ¶ 5, citing paragraphs 13, 14 and 16 of the Application, by way of example.

Based on at least the foregoing, one of ordinary skill in the art upon reading the Application would understand that the post-operative dressing disclosed and described in the Application is designed to be applied within 10 days of amputation of the limb and not intended for ambulation or to promote ambulation. Farraday Declaration ¶ 6.

Based on the materials used in connection with the dressing and the manner and orientation in which they are formed, together with the fact that the dressing is intended to be applied within 10 days of amputation, one of ordinary skill in the art would also understand that the post-operative dressing disclosed and described in the Application is a non-weight bearing device and is not intended to walk on or with. Farraday Declaration ¶ 7. This is further supported by the fact that the Application discloses that the dressing is particularly suited for amputees that “have no potential for ambulating” as disclosed in paragraph 34 of the Application. Farraday Declaration ¶ 7.

Based on the foregoing, Applicant respectfully maintains that it would be clear to one of ordinary skill in the art that the Application as filed is directed towards a non-weight bearing post-operative rigid protective dressing for a limb, and that the post-operative dressing is designed to be applied in the operating room or recovery rooms immediate post surgery or within 10 days of amputation of the limb. Farraday Declaration ¶¶ 4-7. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 12 and 16 under 35 U.S.C. §112, first paragraph.

**Rejection under 35 U.S.C. §103(a)**

Claims 12-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,571,208 to Caspers (“Caspers”) in view of U.S. Patent No. 5,830,237 to Kania (“Kania”) and U.S. Patent No. 6,368,357 to Schon et al. (“Schon”) and Application Publication

No. 2003/0114783 to Vanden ("Vanden"). Claims 16 and 18-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Caspers in view of Kania and Vanden. Dependent claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Caspers in view of Kania and Vanden further in view of Schon.

Applicants respectfully submit that the references, either taken alone or in combination, fail to teach or suggest "providing a non-weight bearing post-operative protection to a limb within ten days from amputation of a limb" as recited in independent claims 12 and 16.

***None of the references teach or suggest  
"providing a non-weight bearing post-operative protection"***

One of ordinary skill in the art would understand that Caspers, Kania, Schon and Vanden are each directed toward weight bearing devices. Farraday Declaration ¶ 11. As such, Caspers, Kania, Schon and Vanden each teach away from the invention as claimed. In addition, Caspers, Kania, Schon and Vanden do not teach or suggest to one of ordinary skill in the art "providing a non-weight bearing post-operative protection to a limb within ten days from amputation of a limb" as recited in independent claims 12 and 16 of the Application. Farraday Declaration ¶ 10. Rather, one of ordinary skill in the art would understand that Caspers, Kania, Schon and Vanden each keep and promote weight bearing and ambulation potential. Farraday Declaration ¶ 10.

Casper describes the liner and sleeve for "donning over a residual limb and fitting within the socket of an artificial limb." (Abstract; Col. 3, lines 54-55). Casper continues to describe the drawbacks associated with artificial limbs and their socket liners available, and further describes its liner as being used for artificial limbs. One of ordinary skill would understand that an artificial limb is a weight bearing device intended for ambulation. Farraday Declaration ¶ 11. In fact, Casper explicitly states that its device is directed toward a "weight bearing" device. ( Col. 3, line 46; col. 6, line 62; col. 7, lines 1-5; col. 9, lines 9). Accordingly, Casper does not teach or

suggest to one of ordinary skill in the art “providing a non-weight bearing post-operative protection” as recited in claims 12 and 16. Farraday Declaration ¶ 11.

Kania is also directed to a fabric-lined (i.e., non-transparent) gel for use with a weight bearing device, and more specifically for providing cushioning between a limb and a prosthetic device. Farraday Declaration ¶ 12. For example, Kania describes the use of fabric-lined gels for minimizing the discomfort of “a prosthetic device, such as an artificial arm or leg.” (Col. 1, lines 18-20) and to provide cushioning “between the residuum and a prosthetic device socket.” (Col. 3, lines 56-59; col. 4, lines 1-2; col. 6, line 67 to col. 7, line 1). Accordingly, one of ordinary skill in the art would understand that Kania is directed towards a weight bearing device intended for ambulation and that Kania does not teach or suggest to one of ordinary skill in the art a “non-weight bearing” device as claimed in the Application. Farraday Declaration ¶ 12.

Schon is also directed to a weight bearing device intended for ambulation. Farraday Declaration ¶ 13. For example, Schon provides that its system “could also be used with an attachable pylon and foot to promote symmetrical body image and the psychological well-being of the amputee, and will also permit early partial weight bearing” (Col. 2, lines 40-43), leading one of an ordinary skill in the art to expect ambulation capability. Farraday Declaration ¶ 13. Schon also states “[t]he use of the therapeutic device 20 of the present invention in conjunction with a pylon 60 and foot 62 immediately after surgery helps the amputee develop balance and a tolerance to weight bearing and prevents contractures and loss of muscle strength.” (Col. 6, lines 54-59). Accordingly, one of ordinary skill in the art would understand that Schon is directed towards a weight bearing ambulating device, and Schon does not teach or suggest to one of ordinary skill in the art a “non-weight bearing non ambulating” device as recited in claims 12 and 16. Farraday Declaration ¶ 13.

Vanden is also directed to a weight bearing device. Farraday Declaration ¶ 14. Thus, Vanden also teaches away from the invention as claimed. Vanden is directed to an orthopedic device having a clam shell having an implement attached thereto. One of ordinary skill in the art would understand that such a device is a weight bearing device. Farraday Declaration ¶ 14. Furthermore, Vanden is directed to addressing hand and wrist dysfunctions, and not a recently amputated residual limb as described and claimed in the Application. One of ordinary skill in the art would understand that a non-weight bearing device lacking an implement would defeat the objectives of Vanden and render it unsuitable for its intended purpose. Farraday Declaration ¶ 14. Thus it would not have been obvious (or desirable) to one of ordinary skill in the art to modify Vanden to provide a non-weight bearing device. Farraday Declaration ¶ 14.

**None of the references teach or suggest a device provided “within ten days from amputation”**

Casper, Kania, Schon and Vanden do not teach or suggest to one of ordinary skill in the art that the devices disclosed therein are to be applied “within ten days from amputation” as recited in claims 12 and 16 of the Application. Farraday Declaration ¶ 15.

In fact, Casper, Kania and Vanden are not directed to “recently amputated residual limb” or to treating a residual limb within ten days of amputation. One of ordinary skill in the art would understand that the weight bearing devices disclosed in Casper, Kania and Vanden would not be provided on a recently amputated residual limb. Farraday Declaration ¶ 15. To do so would likely apply too much pressure on the residual limb and would not compress and contain the limb. Farraday Declaration ¶ 15. One of ordinary skill in the art would understand that the devices described Casper, Kania and Vanden would not be suitable for a recently amputated residual limb within ten days from amputation. Farraday Declaration ¶ 15. Modifying Casper, Kania and Vanden to provide such a method and device would render Casper, Kania and Vanden

unsuitable for their intended purposes. Accordingly, not only do Casper, Kania and Vanden fail to teach or suggest “within ten days from amputation” but rather, teach away from such claim limitations.

Schon is directed to post-operation treatment and teaches away from the invention as claimed, and more specifically, “compressing and containing the recently amputated residual limb by applying a thermo plastic gel liner on the recently amputated residual limb.” Schon provides:

Notably, because of its unique configuration, the therapeutic device 20 of the present invention **need not be custom molded to a particular user, but rather may be used to fit amputees of varying sizes**. Once the residual limb 10 is placed within the shell 22 and the second shell portion 26 moved to envelop the limb 10, the fastening means 30 may be adjusted as needed to secure the shell 22 in a closed position about the circumference of the limb. **The bladders 40 may then be suitably inflated to essentially encompass the entire circumferential surface of the residual limb 10 and provide a comfortable, soft interface.**

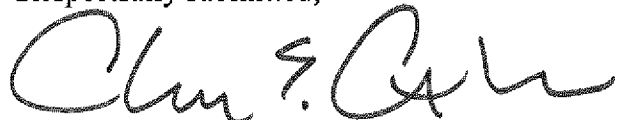
(Col. 5, line 59 to col. 6, line 2). Accordingly, Schon fails to teach or suggest “applying a thermo plastic gel liner on the recently amputated residual limb” for “compressing and containing the recently amputated residual limb.” In contrast, Schon teaches **not** to provide custom molding the orthotic and instead, stating that it is beneficial to inflate bladders to encompass the surface of the residual limb. Accordingly, Schon teaches away from the invention as claimed. Furthermore, Schon, which teaches away from a custom molded device, teaches away from the invention, which provides the steps of wrapping the residual limb with gauze to create a custom made cast as claimed.

At least for the reasons set forth above, Applicants respectfully maintain that independent claims 12 and 16 are patentable over Caspers in view of Kania, Vanden and Schon, either taken alone or in any combination thereof. In the interest of brevity, Applicants also respectfully

maintain that dependent claims 13-15 and 17-22 are also patentable over Caspers in view of Kania, Vanden and Schon, and the merits of the rejections will not be addressed in detail herein.

No fee, other than the three-month extension of time and the fee submitted herewith, is deemed necessary in connection with the filing of this Request for Reconsideration. However, if any additional fee is required, the Examiner is hereby authorized to charge the amount of such fee to Deposit Account No. 19-4709.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles E. Cantine", written over a horizontal line.

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